TUCKER ELLIS LLP
MOLLIE F. BENEDICT SBN 187084
mollie.benedict@tuckerellis.com
MONEE TAKLA HANNA SBN 259468
monee.hanna@tuckerellis.com
515 South Flower Street, 42nd Floor
Los Angeles, CA 90071-2223
Telephone: 213.430.3400
Facsimile: 213.430.3409

TUCKER ELLIS LLP
DUSTIN B. RAWLIN *appearance pro hac vice*
dustin.rawlin@tuckerellis.com
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5009

Attorneys for Defendant MENTOR WORLDWIDE LLC

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

REXINA MIZE, an individual; MINH NGUYEN, an individual; Plaintiffs, v. MENTOR WORLDWIDE LLC; and DOES 1-100, inclusive, Defendants.	CASE NO.: 2:17-cv-01747-DMG-KS Hon. Dolly M. Gee **REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF MENTOR'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT PURSUANT TO RULE 12(b)(6)** [Filed concurrently with Notice of Motion and Motion to Dismiss; Memorandum of Points and Authorities, Declaration of Mollie F. Benedict, and [Proposed] Order] **DATE:** June 16, 2017 **TIME:** 9:30 A.M. **Courtroom:** 8C

Pursuant to Rule 201 of the Federal Rules of Evidence, Defendant Mentor Worldwide LLC respectfully requests that the Court take judicial notice of the documents of the following documents:

(1) November 17, 2006 Premarket Approval (PMA) letter from the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)

granting PMA to Mentor Corporation for Mentor MemoryGel Silicone Breast Implants, attached as **Exhibit 1**. This FDA PMA letter is publicly available on the FDA's website at https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030053A.pdf (last visited May 15, 2017);

(2) Federal Register/Vol. 72, No. 63, April 3, 2007 Notices, TABLE 1: List of Safety and Effectiveness Summaries for Approved PMAs Made Available from October 1, 2006 to December 31, 2006, which identifies the FDA's November 17, 2006 PMA approval of Mentor MemoryGel™ Silicone Gel-Filled Breast Implants, attached as **Exhibit 2**. This section of the Federal Register is available at https://www.gpo.gov/fdsys/pkg/FR-2007-04-03/pdf/E7-6166.pdf (last visited May 15, 2017);

(3) FDA Update on the Safety of Silicone Gel-Filled Breast Implants, Executive Summary, attached as **Exhibit 3**. This FDA document is available at https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM260090.pdf (last visited May 15, 2017);

(4) FDA On-Line Database entry for Mentor MemoryGel Silicone Breast Implants, PMA Supplement for P030053, attached as **Exhibit 4**. This FDA document is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030053S035 (last visited May 15, 2017).

Courts may take judicial notice of facts that are not subject to reasonable dispute. *Lee v. City of Los Angeles*, 250 F.3d 668, 688–89 (9th Cir. 2001). A fact is not subject to reasonable dispute when it is "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." FED. R. EVID. 201. Federal courts, including in California, regularly take judicial notice of prescription drug labels and other FDA documents because these documents are not subject to reasonable dispute. *See Wilson v. Amneal Pharms., L.L.C.*, 2013 WL 6909930, at *4–7 (D. Idaho Dec. 31, 2013) (taking judicial notice of FDA approval letters and drug labels, including those found on FDA's website); *In re Amgen Inc., Sec. Litig.*, 544 F. Supp. 2d 1009, 1023

(C.D. Cal. 2008) (taking judicial notice of drug labels obtained from FDA's website "as documents 'capable of accurate and ready determination' and 'not subject to reasonable dispute'"); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1286 (C.D. Cal. 2008) (same).

Further, judicial notice of an FDA letter is proper because letters sent from government agencies are public records, the contents of which are not reasonably in dispute. *See Assoc. of Irritated Residents v. Fred Schakel Dairy*, 460 F. Supp. 2d 1185, 1188 (E.D. Cal. 2006) (granting request for judicial notice of letter to defendants from local air pollution control district).

Additionally, because PMA approvals are documented in the Federal Register, courts are required to take judicial notice of them. *See* 21 C.F.R. § 814.44(d)(1) (2010) ("FDA will publish in the Federal Register after each quarter a list of the approvals announced in that quarter."); 44 U.S.C. § 1507 ("[t]he contents of the Federal Register shall be judicially noticed.").

DATED: May 16, 2017

TUCKER ELLIS LLP

By: */s/Mollie F. Benedict*
Mollie F. Benedict
Attorneys for Defendant MENTOR WORLDWIDE LLC

CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of May, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which shall send notification of such filing.

/s/ *Mollie F. Benedict*
Mollie F. Benedict